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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte CLAUDIA CHERNEY STEWART

Appeal 2008-2750
Application 09/330,629
Technology Center 1600

Decided: September 22, 2008

Before ERIC GRIMES, RICHARD M. LEBOVITZ, and MELANIE L. McCOLLUM, *Administrative Patent Judges*.

McCOLLUM, *Administrative Patent Judge*.

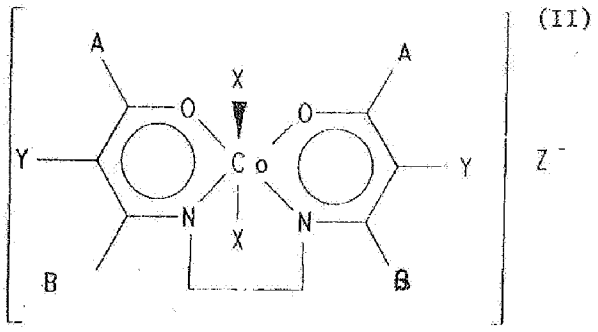
DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method for prophylactically reducing the risk of transmission of an HIV infection. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

INTRODUCTION

Claims 41-53 are on appeal. The claims have not been argued separately and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii). We will focus on claim 41, the broadest claim on appeal, which reads as follows:

41. A method for prophylactically reducing the risk of transmission of Human Immunodeficiency Virus infection to a recipient and protecting the recipient from infection with Human Immunodeficiency Virus infection comprising topically applying a Human Immunodeficiency Virus infection prophylactic effective amount to that site on the recipient which is subject to exposure to Human Immunodeficiency Virus infection a composition comprising a Human Immunodeficiency Virus infection prophylactic effective amount of a compound having the structure

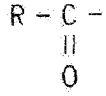


(II)

wherein each

A is the same or different and is an alkyl group, a phenyl group or a substituted derivative of a phenyl group;

Y is the same or different and is hydrogen, an unbranched alkyl group, a halide or a group having the structure

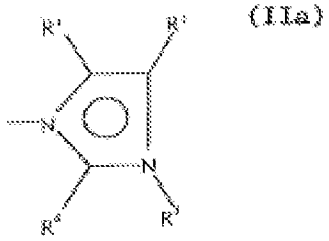


wherein R is hydrogen, an alkoxide group, an alkyl group, or OH;

B is the same or different and each is hydrogen or an alkyl group;

Z^- is a soluble, pharmaceutically acceptable negative ion; and

X is the same or different and is an axial ligand selected from the group consisting of moieties having the formula:



wherein R^1, R^2, R^3, and R^4 are the same or different and may be hydrogen or lower alkyl having from 1 to 4 carbon atoms;

with the proviso that R^1, R^2, R^3, and R^4 are of a sufficiently small size so as not to prohibit the attachment of the axial ligand to the Co atom due to steric hindrance.

DOUBLE PATENTING

Claims 41-53 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-12 of U.S. Application No. 10/662,848[1] in view of Fields[2] (Ans. 3). Appellant does not traverse this rejection (Br. 4). Therefore, we affirm it.

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[1] During the course of this appeal, it appears that U.S. Application No. 10/662,848 has been abandoned, but that a division of that application, U.S. Application No. 11/778,706, has been filed. The claims of the '706 application appear to be of the same scope as the claims of the '848 application that were relied on by the Examiner.

[2] FIELDS VIROLOGY, pp. 26-27 (3rd ed. 1996).

OBVIOUSNESS

Claims 41-53 stand rejected under 35 U.S.C. § 103(a) as obvious over Dori[3] in view of Cooper,[4] Fields, and Merck Manual[5] (Ans. 4-5).

The Examiner relies on Dori for teaching "the method of treating viral infection and decreasing viral titer broadly by topically administering the metallo-organic cobalt compounds, including compound No. 96 in the instant specification, with a concentration of 0.5 to 10mg/ml (0.05 to 1% by wt)" (*id.* at 5). The Examiner finds that Dori teaches that "the metallo-cobalt compounds are useful in treating viral infection broadly, especially for viruses which are well-known in the art, such as listed in Field[s] et al., Virology" (*id.*). The Examiner also finds that Dori "teaches the dosage form of the metallo-organic cobalt compounds may be ointments, salves, and creams" (*id.*).

The Examiner relies on Cooper for teaching that "a method of topical administration of a medical agent by applicators including a condom is known in the art" (*id.*). The Examiner relies on Fields for teaching "the common viral pathogens in human[s]" (*id.*). The Examiner relies on Merck Manual for teaching "employing anti-infective agents (both antiviral and antibacterial) in antimicrobial chemoprophylaxis as common practice in the pharmaceutical field" (*id.* at 6). The Examiner concludes that it would have been obvious "to topically administer the instant compounds . . . for the prophylaxis of HIV infection" (*id.*).

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[3] WO 93/11140, Jun. 10, 1993.
[4] US 4,242,359, Dec. 30, 1980.
[5] THE MERCK MANUAL, pp. 49-55 (16th ed. 1992).

Appellant contends that the Examiner erred in concluding that the applied references teach or suggest a prophylactic method (Br. 7).

Findings of Fact

1. The Specification discloses the use of metallo-organic compounds "in the prophylactic treatment of subjects (animals or human) to prevent human immunodeficiency virus (HIV)" infection (Spec. 1: 2-4).

2. The Specification states that these compounds "exhibit prophylactic efficacy when applied as a topical composition to the contact site prior to contact with HIV . . . , and/or by inactivating HIV . . . exposed to the composition, and/or by preventing expression of HIV . . . disease" (*id.* at 3: 16-19).

3. The term "prophylaxis" is defined as the "[p]revention of disease or of a process that can lead to disease." Stedman's Medical Dictionary (27th ed. 2000) (definition attached).

4. Dori discloses "metallo-organic cobalt compounds and their use in the treatment of subjects for conditions and diseases caused by viruses and viral infections" (Dori 1: 17-20).

5. Dori also discloses antiviral compositions comprising these compounds "in an amount effective to suppress the replication and/or abort the infective life cycle of the virus causing the infection" (*id.* at 6: 5-9).

6. In addition, Dori discloses administering its antiviral compositions using conventional modes, including topical application (*id.* at 6: 1-4).

7. Dori also discloses that its "compounds are particularly effective against, *inter alia*, herpes virus" (*id.* at 12: 8-9).

8. However, Dori discloses that the "compounds and compositions may be used in treating infections caused by a variety of viruses" and that "[k]nown viruses of clinical significance are disclosed in . . . Virology, B. N. Fields [et al.] . . . (1985)" (*id.* at 11: 19 to 12: 4).

9. Specifically, Dori discloses a compound referred to therein as Compound 96, as well as a compound referred to therein as Compound 82 (*id.* at 4 & 9-10), both of which are within formula (II) of present claim 41.

10. Dori includes an example (Example 6) disclosing the activity of Compound 82 in a primary genital HSV-2 infection (*id.* at 42-48).

11. In this example, guinea pigs infected with HSV-2 were treated with Compound 82 topically -- 2 mg (0.1 ml of composition having a concentration of 20 mg/ml) intravaginally and 2 mg on the external genital skin (*id.* at 43: 5-23).

12. Dori states that "[e]arly treatment with [Compound 82] reduced the number of animals that became infected with HSV-2 (had virus isolated on at least one swab day)" (*id.* at 45: 11-13).

13. Fields discloses that human immunodeficiency viruses 1 and 2 are pathogenic viruses of humans (Fields 26).

14. Merck Manual discloses that "**[z]idovudine (ZDU)**, formerly called azidothymidine **(AZT)**, is . . . [a] potent inhibitor[] of replication of the human immunodeficiency virus (HIV) in vitro," and that it "results in longer survival of patients with AIDS and . . . retard[s] the onset of clinical disease in patients infected or minimally symptomatic from their HIV infection" (Merck Manual 55).

15. Merck Manual also discloses that "ZDU is used for prophylaxis following high-risk exposure (eg, needlestick injuries), but it has not been shown to be effective for that purpose" (*id.*).

16. Cooper discloses a topical composition in the form of a cream to coat a condom (Cooper, col. 8, ll. 37-43).

Analysis

Claim 41 comprises topically applying to that site on a recipient that is subject to exposure to HIV infection a composition comprising an HIV prophylactic effective amount of a compound of formula (II). In Example 6, Dori discloses topically applying intravaginally and on the external genital skin a composition comprising a compound within formula (II) (Findings of Fact (FF) 9-11). Dori states that the treatment "reduced the number of animals that became infected with HSV-2" (FF 12). We find that there is a prima facie case that the amount administered in Dori Example 6 is an HIV prophylactic effective amount because an amount that reduces infection by HSV-2 would reasonably appear to reduce infection by other viruses, including HIV.

The preamble of claim 41 states that the method is "for prophylactically reducing the risk of transmission of HIV infection to a recipient and protecting the recipient from infection with HIV infection." We find that this preamble language is "only a statement of purpose and intended result. The expression does not result in a manipulative difference in the steps of the claim." *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1376 (Fed. Cir. 2001). In addition, the Specification discloses that prophylactically reducing the risk of transmission of HIV

infection is an inherent result of topically applying a compound of formula (II) at a viral contact site (FF 1-2). Therefore, we conclude that Dori anticipates claim 41. "[A]nticipation is the epitome of obviousness." *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983).

In addition, although not necessary based on our interpretation of claim 41, we agree that the Examiner has set forth a prima facie case that it would have been obvious to administer the compounds taught by Dori prophylactically to protect the recipient from an HIV infection. In particular, Dori discloses that "[e]arly treatment with [Compound 82] reduced the number of animals that became infected with HSV-2" (FF 12). In addition, Dori discloses that the "compounds and compositions may be used in treating infections caused by a variety of viruses" (FF 8).

Although Dori does not appear to specifically mention HIV, it was a known virus of clinical significance at the time of the invention and, in fact, it is specifically mentioned in at least a later edition of Fields, a book relied upon in Appellant's Specification as disclosing "[k]nown viruses of clinical significance" (FF 8 & 13). In addition, Merck Manual discloses that ZDU (AZT), an inhibitor of HIV replication that is used to treat HIV infections, is also "used for prophylaxis following high-risk exposure (eg, needlestick injuries)" (FF 14-15). Thus, we agree that the Examiner has set forth a prima facie case that one of ordinary skill in the art would have been motivated to use Dori's compounds prophylactically to protect the recipient from an HIV infection. In addition, based on the teachings in Dori Example 6 that "[e]arly treatment with [Compound 82] reduced the number

of animals that became infected with HSV-2" (FF 9-12), we agree that there would have been a reasonable expectation of success.

Appellant argues, however, that "prophylaxis . . . means that a drug is used which interacts with the virus outside of the cell prior to its entry and which prevents the virus from entering the cell and initiating an infection" (Br. 5). In particular, Appellant argues that "Compound CTC-96 achieves this with both HIV and HSV[, but that m]ost drugs against these and other viruses act on virus replication once it is already inside the cell" (*id.*). In contrast, Appellant argues that the articles submitted by Appellant, in particular Schwartz,[6] "support the fact that the invention as recited in the claims with respect to the compounds referred to therein do exert a prophylactic effect by acting on the virus outside the cell" (*id.*).

We are not persuaded by the argument. The term "prophylaxis" refers to the "[p]revention of disease or of a process that can lead to disease" (FF 3). Appellant has not provided sufficient evidence that this term is limited to the use of drugs that prevent the virus from entering the cell. Thus, we do not agree that the term should be interpreted to require the use of such a drug.

We conclude that the Examiner has set forth a prima facie case that claim 41 would have been obvious over Dori in view of Cooper, Fields, and Merck Manual, which Appellant has not rebutted. We therefore affirm the

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[6] Jennifer A. Schwartz et al., *Herpes Simplex Virus Type 1 Entry Is Inhibited by the Cobalt Chelate Complex CTC-96*, 75 JOURNAL OF VIROLOGY 4117-4128 (2001).

rejection of claim 41 under 35 U.S.C. § 103(a). Claims 42-53 fall with claim 41.

CONCLUSION

The Examiner's position is supported by the preponderance of the evidence of record. We therefore affirm the rejections of claims 41-53 under the judicially created doctrine of obviousness-type double patenting and under 35 U.S.C. § 103(a).

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

dm

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